REMARKS

In accordance with the above amendments, claims 135, 137, 152, 154, 168, 183, 185, 193, 195 and 203 have been amended. Claims 135-144, 152-161, 168-176 and 183-211 remain under consideration in the present application. No claim has been allowed.

The amendments to the claims have been made to clarify the claims with regard to the claimed animals. It is noteworthy that the transgenic animals, as claimed, are all endowed with the viral vector (or lentiviral vector) as the case may be in the genome of their cells. The amendment of the term "agent" to "gene product" in claim 135 further makes the claim more internally consistent.

Applicants further believe that more than sufficient support is found in the specification for the amendments. For example, on page 5, lines 5-13, the application teaches viral vectors (line 10) and introduction into the genome of the germ cells (line 13). Additional support is found in original claims 2 and 3, in particular, claim 3 refers to lentiviral vectors. See also page 13, lines 6-9, which clearly convey that the genetic material is integrated into the chromosomes ("stable transfection"). With regard to the amendment of the term "agent" to "gene product", reference is made to page 15, line 25 through page 16, line 6. It is described that the "agents which are of

therapeutic benefit" are products of the polynucleotide introduced into the transgenic animal.

Claims 135-144, 152-161 and 168-176 stand rejected in the Office Action based on 35 USC § 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which the applicants regard as their invention. This rejection is respectfully traversed.

It is believed that the claims are and, specifically, independent claim 135, perfectly clear, particularly in view of the present amendments. Applicants believe that the skilled person would readily know whether a particular polynucleotide falls within the definition or not. Applicants cannot agree that the "metes and bounds" would rely on the use, not the product made". It is believed that the language of the claims provide the necessary functional parameters that the polynucleotides have to fulfill. These are commonly used to define products (polynucleotides) in a manner readily understood by those skilled in the art and, in particular, as will be discussed, it is plain that an oncogene does not fall within this definition.

Therefore, it is believed that claim 135-144, 152-161 and 168-176 are sufficiently definite to impart clear meaning to those skilled in the art and reconsideration and withdrawal of the rejection under 35 USC § 112, second paragraph, is respectfully requested.

Previous withdrawal of the rejection under 35 USC § 112, first paragraph, and non-statutory double-patenting are gratefully acknowledged.

It is noted that the pending claims have further been rejected under 35 USC § 102(e) as being anticipated by Brinster et al (USPN 5,858,354) and Deboer et al (USPN 5,741,957). This rejection is respectfully traversed.

As is well known, in order for a rejection to stand under 35 USC § 102, the reference must disclose or teach each and every element or limitation of the corresponding claim. Here, there are clear differences between the transgenic animals claimed in the present application and those of the above-cited references. It should well be appreciated that the transgenic animals claimed all contain in their genomes some viral DNA from the vector. Thus, the transgenic animals of claims 135, 152 and 168 (and claims dependent thereon) are distinguished from the animals describe in Brinster et al and Deboer et al which (as we have explained in detail previously) do not contain any viral vector DNA in their genome.

The above difference clearly is sufficient to distinguish the claimed transgenic animals from those of the cited references, with the amendments made to the claims highlighting the difference by explicitly indicating that the viral vector is integrated into the genome of the animal cells.

Reconsideration and withdrawal of this rejection is respectfully requested.

Finally, claims 135-144, 152-161, 168-176 and 184-211 stand rejected under 35 USC § 102(b) as being anticipated by Leder (USPN 4,736,866). This rejection is also respectfully traversed.

In this regard, it is noted at the outset that Leder et al relates solely to the expression of an oncogene. Of course, an oncogene product is not a gene product that is of any therapeutic benefit for use in human or veterinary medicine or well being and therefore clearly does not meet the requirements of the present claims. Therefore, the rejection of the claims under 35 USC § 102(b) based on Leder et al should not stand and reconsideration and withdrawal of this rejection is respectfully requested.

In order to better explain the present invention in contrast to the cited references, certain additional comments are provided as, it is believed, that they would be helpful in the examination of this application.

Claims 183-210 are directed at transgenic animals containing lentiviral vectors. The transgenic animals claimed will all contain in the genome of their cells some lentiviral DNA from the vector. None of the prior art describes animals which are transgenic with a lentiviral vector or which contain lentiviral DNA in their genomes.

Again, this difference is sufficient to establish novelty,

and the amendments to the claims highlight this difference.

In relation to the Examiner's rejection based on Leder et al, the Examiner appears to take the position that the model generated by Leder et al is useful in studying "human or veterinary medicine" or studying "well being". In this regard, the Examiner is asked to carefully reconsider the present claim language which indicates that the polynucleotide expresses an agent (now amended to "gene product") which is of <u>therapeutic benefit for use in human or veterinary medicine or well being</u>. It is difficult to see how expression of an oncogene (which causes cancer) is of therapeutic benefit of can be <u>used</u> in human or veterinary medicine or well being.

It should be note with respect to claims 183-210 that the above claim language is not included. However, the claims are novel over Leder et al (and the other references) in any event because there is no disclosure of a lentiviral vector having been used in the prior art (or incorporated into the genome of a transgenic animal). The Examiner has explicitly acknowledged this on page 8 of the Office Action. However, contrary to the Examiner's assertion, there <u>is</u> a structural limitation in the claim which distinguishes the animals from Leder et al. The presence of the lentiviral vector in the genome of the transgenic animals is a clear structural difference which can readily be tested (for example, using Southern blotting or PCR). Lentiviral

vectors are integrative vectors which integrate into the genome of their host cell.

In view of the above amendments, taken together with the remarks herein, the Examiner is asked to reconsider, withdraw the present rejections and allow all of the claims.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that the foregoing Amendment in response to the Official Action of September 23, 2005, a Transmittal Letter, a Petition for a three-month extension of time and a check in the amount of $1020.00 in application Serial No. 10/054,365, filed on November 12, 2001, of Carol W. Readhead et al, entitled "TRANSFECTION, STORAGE AND TRANSFER OF MALE GERM CELLS FOR GENERATION OF TRANSGENIC SPECIES & GENETIC THERAPIES" are being deposited with the U.S. Postal Service as First Class mail in an envelope addressed to Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, postage prepaid, on March 21, 2006.

Barbara L. Davis
on behalf of C. G. Mersereau
Attorney for Applicant

Date of Signature: March 21, 2006